REMARKS

Claims 1-27 are pending in this application. Claims 1 and 14 have been amended for clarity.

1. Claim rejections under 35 U.S.C. § 112, first paragraph

Claims 1-27 are rejected as failing to comply with the written description requirement. The Examiner argues that the specification does not describe a "means for preventing switching to a DDD pacing mode" and "when a condition indicative of a suspected loss of atrial detection is detected". Specifically, the Examiner argues that while the specification states that the "detection and correction of the defects of atrial capture or atrial under-detection are employed to avoid an inappropriate switching to operating in a conventional DDD operating mode" the specification does not state that there is some element or step used to prevent switching to a DDD pacing mode and/or used to prevent switching when a condition indicative of a suspected loss of atrial detection is detected. Applicant respectfully traverses this ground of rejection.

Applicant submits a Declaration under 37 C.F.R. 1.132 by Dr. Philippe Mabo (Exhibit A) attesting to the fact that Applicant's disclosure in the specification would have reasonably conveyed to a person of ordinary skill in the art that the inventor had possession of the claimed invention at the time the application was filed. The Declaration was not previously submitted because the Examiner's rejection under 35 U.S.C. § 112, first paragraph alleging that the claims do not comply with the written description requirement was first made in the March 18, 2008 Office Action. This is the first time Applicant is responding to a rejection on these grounds. Accordingly, Applicant respectfully submits that good and sufficient reasons are shown as to why this response and the accompanying Declaration by Dr. Philippe Mabo should be considered

in this after final Amendment.

Applicant initially notes that amended independent claims 1 and 14 now recite, among other things, "means for avoiding inappropriate switching to a DDD pacing mode when a condition indicative of a suspected loss of atrial detection is detected"; and independent claim 21 recites, among other things, "means for analyzing said sequence to detect a condition indicative of a suspected loss of atrial detection in order to prevent inappropriate switching to a DDD pacing mode".

The specification teaches in the Background of the Invention:

> The quality of the detection of spontaneous cardiac signals and the quality of the capture of a stimulated cardiac event are essential to the effectiveness of the various analysis and control algorithms that are integrated into the implanted devices. Parameters are available for this purpose to allow the doctor to adjust the sensitivity of detection of spontaneous activity and the stimulation energy level necessary to stimulate a cardiac contraction (i.e., a capture) as best as possible.

See page 2, lines 2-7.

Further, in the Objects and Summary of the Invention, the specification teaches:

> [I]t is an object of the invention to improve the auto-adjustment of the sensitivity and the stimulation energy values, suitable to avoid inopportune and useless misadjustments of these parameters. Broadly, the present invention concerns improved apparatus and signal processing methods that detect situations of atrial under-detection and loss of atrial capture, to be able to ensure the correct operation of the various algorithms operating the device. One aspect of the invention is directed to a device that is equipped with an automatic commutation operation, in which the detection and correction of the defects of atrial capture or under-detection are employed **to avoid an inappropriate switching** to operating in a conventional DDD operating mode. This avoids unnecessarily stimulating the ventricle, and thus mitigates the possible noxious effects, from the hemodynamic point of view, of delivering such an inappropriate therapy.

See page 2, line 15 through page 3, line 4 (emphasis supplied). The specification further teaches:

> Advantageously, the suspecting means also is able to deliver an atrial counter-stimulation of relatively increased energy, in the event of an absence of

> ventricular activity post-atrial stimulation. This delivery may actually occur indirectly, that is, by controlling the appropriate stimulation to deliver a stimulation pulse at the desired energy level as the counter-stimulation pulse.

See page 4, lines 1-5.

The specification specifically contemplates the device avoiding inappropriate switching to a DDD pacing mode when a condition indicative of a suspected loss of atrial detection is detected. The specification teaches:

> If the atrial activity is systematically a stimulated activity (Stimulation A), the device initially suspect a loss of atrial capture. In this case, the energy of the following stimulation is increased, with the parameterized value (maximum energy or an energy corresponding to a step above the current energy). Then, if the normal atrio-ventricular conduction delay is restored (the upper chronogram of Fig. 2), the device returns to its initial operation mode AAI, without AVD, with an increased stimulation energy.

See page 9, lines 12-17.

The specification also teaches three cases of management of loss of atrial detection. *See* page 10, line 19 through page 11, line 19 and Figs. 4 and 5. In these cases, if the device suspects a loss of atrial detection, the device increases atrial sensitivity. *See, e.g.*, page 10, line 19 through 11, line 4; page 11, lines 6-11; page 11, lines 12-15. This is a step taken to avoid inappropriate switching to a DDD pacing mode.

The specification incorporates by reference United States Patent No. 5,318,594 ("the '594 patent"). The '594 patent discloses:

> It is another object of this invention to provide a cardiac pacemaker of the DDD type that will operate in the DDD mode solely during period of crisis, and will operate in the AAI mode outside of the period of crisis.

See '594 Patent, Col. 1, line 67 through Col. 2, line 2.

The present invention ensures correct operation of the various algorithms operating the

device through improved apparatus and signal processing methods that detect situations of atrial under-detection and loss of atrial capture, to be able to ensure the correct operation of the various algorithms operating the device. An automatic commutation operation, in which the detection and correction of the defects of atrial capture or under-detection are employed, avoids unnecessarily stimulating the ventricle and mitigates the possible noxious effects of delivering inappropriate therapy. Prior art signal processing methods may have mistakenly interpreted detection of situations of atrial under-detection and loss of atrial capture. The prior art signal processing methods may have interpreted these situations as a period of crisis and switched to operation in DDD mode. However, this invention discloses an active implantable medical device comprising a means for preventing switching to a DDD pacing mode when a condition indicative of a suspected loss of atrial detection is detected.

Applicant believes that the claims are supported by the specification as filed and confirmed by the comments of Dr. Philippe Mabo in his Declaration and respectfully asks the Examiner to reconsider and withdraw the § 112 rejection based on written description.

CONCLUSION

Reconsideration of this application in view of the foregoing remarks respectfully is requested. The Examiner is invited to call Applicant's undersigned attorney if doing so would expedite prosecution.

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EXHIBIT A